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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,711	03/20/2006	Gregg Bogosian	11916.0059.PC/US01	5263
45607 7590 03/21/2008				
HOWREY LLP				
C/O IP DOCKETING DEPARTMENT				
2941 FAIRVIEW PARK DRIVE SUITE 200				
FALLS CHURCH, VA 22042				
EXAMINER				
PAK, YONG D				
ART UNIT		PAPER NUMBER		
1652				
MAIL DATE		DELIVERY MODE		
03/21/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/572,711

Applicant(s)

BOGOSIAN ET AL.

Examiner

Yong D. Pak

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-42 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF 298)
Paper No(s)/Mail Date ____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

This application is a 371 of PCT/US04/31224.

Claims 1-42 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-18 and 41, drawn to a method for reducing the incorporation of non-standard amino acids into a heterologous protein by using a microorganism expressing (1) at least one heterologous protein selected and (1) at least one non-standard amino acid degrading protein.

Group II, claim(s) 19-20 drawn to an *E. coli* glutamate dehydrogenase protein comprising a lysine 92 to leucine variation or an *E. coli* glutamate dehydrogenase having the sequence of SEQ ID NO:4.

Group III, claim(s) 21-41, drawn to a polynucleotide encoding the glutamate dehydrogenase of Group II and cell comprising said polynucleotide and a method of isolating a protein using a cell expressing (1) at least one heterologous protein selected and (1) at least one non-standard amino acid degrading protein.

In addition, applicants are required to elect ONE polynucleotide sequence encoding (1) a heterologous protein selected from somatotropin isolated from human, equine, bovine, ovine, procaine, canine or feline and (1) at least one non-standard amino acid degrading protein selected from SEQ ID NO:2, 4, 6, 8, 10, 12, 14 or 16,

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leucine dehydrogenase, phenylalanine dehydrogenase, valine dehydrogenase, opine dehydrogenase. For example, applicant can elect Group I drawn to a method of using a cell expressing the glutamate dehydrogenase of SEQ ID NO:4 and human somatotropin.

This is not an election of species. Each of the polynucleotides/ polypeptides lack the same or corresponding special technical feature and are **patentably distinct inventions**. Each of the polynucleotides/polypeptides have different structure and/or function and encoded polypeptides having different structure and function, such as substrate specificity. Each of the polynucleotides and polypeptides are independent chemical entities and require independent search in the patent and non-patent literature.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups I-III appears to be that they all relate to a non-standard amino acid degrading protein, such as a glutamate dehydrogenase having the amino acid sequence of SEQ ID NO:4 of claim 20.

However, Jones et al. (Mol Gen Genet. 1993 Aug;240(2):286-9 – form PTO-892) discloses a glutamate dehydrogenase having the amino acid sequence of SEQ ID NO:4 (abstract).

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Therefore, the technical feature linking the inventions of Groups I-III does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

The special technical feature of Group I is a method for reducing the incorporation of non-standard amino acids into a heterologous protein by using a microorganism expressing (1) at least one heterologous protein selected and (1) at least one non-standard amino acid degrading protein.

The special technical feature of Group II is an *E. coli* glutamate dehydrogenase protein comprising a lysine 92 to leucine variation or an *E. coli* glutamate dehydrogenase having the sequence of SEQ ID NO:4.

The special technical feature of Group III is a polynucleotide encoding an *E. coli* glutamate dehydrogenase protein comprising a lysine 92 to leucine variation or an *E. coli* glutamate dehydrogenase having the sequence of SEQ ID NO:4 and a cell comprising said polynucleotide and a method of isolating a protein using a cell expressing 1) at least one heterologous protein selected and (1) at least one non-standard amino acid degrading protein.

Accordingly, Groups I-III are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Pak whose telephone number is 571-272-0935. The examiner can normally be reached 6:30 A.M. to 5:00 P.M. Monday through Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nashaat Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

/Yong D Pak/
Primary Examiner, Art Unit 1652